RECEIVED
CENTRAL FAX CENTER
MAR 0 5 2007

--REMARKS--

The Applicant thanks the Examiner for the detailed office action and for agreeing to conduct a telephonic interview. The Applicant has carefully reviewed the statements the Examiner presented in rejecting all of the claims of the application, has also carefully reviewed the cited references upon which the rejections are based, and has carefully considered the Examiners' comments during the February 22, 2007 interview. The Applicant respectfully requests reconsideration and re-examination of the claims of the application in view of the Applicant's amendments and responses to the rejection of the claims presented herein.

Claims Rejections under 35USC §112:

The Examiner rejected Claims 1-4, 6-11, 13-18, 39-41, 48-50, & 53 as failing to comply with the 35USC §112 first paragraph. The Examiner states that the claims contain subject matter which was not described in the Specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner states that the Applicant fails to disclose the nature of the interface of the electronic control unit with the fluid pressure control element to maintain periodic and simulated systolic and diastolic pressure levels in a vessel, nor the nature of the interface between an automatic sphygmomanometer and the Applicant's instant invention that receives blood pressure and pulse rate data to maintain said pressure. The Applicant maintains that the specification is fully enabling to those having ordinary skill in the art in electronic blood pressure technologies or other electro-mechanical devices interfacing with electronic control systems having data feedback as in the instant invention. For example, electronic sensor input into electronic circuit or microprocessor based systems and resulting control of electro-mechanical actuators based on said input have been extensively practiced for decades in the field of the instant invention as well as vast numbers of other electro-mechanical and automation technologies and are extremely well known. Additionally, data interfacing between electronic sensors and actuators has also been extremely well known for decades in numerous electronics products industries including blood pressure device technologies. The Applicant also points to Fig. 1 of the application where it is clear how the system operates. Finally, the Applicant points to the first office action of this application where a previous examiner found the specification enabling in this regard. For the sole purpose of advancing the prosecution of this particular application in response to the Examiner's repeated rejections based on 35USC §112 first paragraph , the Applicant has amended the independent Claims 1 and 39 to overcome this rejection and has canceled Claim 17 without prejudice. By amending Claims 1 and 39 and canceling Claim 17, the Applicant does not admit nor does the Applicant imply that these claims, as previously presented, are not fully enabled by the Specification and knowledge of one having ordinary skill in the art at the time the invention was made. It is noted that Claims 48 and 49 have been canceled since amended Claim 39 incorporates the elements of previously presented Claims 48 and 49. The remaining Claims 2-4, 6-11, 13-16, 18, 40-41, 50, & 53 are dependent claims depending on either amended Claim 1 or Claim 39. The Applicant respectfully requests that the rejections of all of the above active independent and dependent claims based on 35USC §112 first paragraph be withdrawn.

Claims Rejections under 35USC §102(b):

Claims 1 and 13 are rejected by the Examiner under 35USC §102(b) as being anticipated by Pickering et al (US 6,168,567) hereafter known as Pickering. Claim 1 is an independent claim on which Claim 13 depends.

The Examiner describes Pickering as disclosing each element of Claim 1 including a tactile interface where a human can sense by touch pressure amplitudes within the vessel which are maintained periodic to simulate systolic and diastolic blood pressure levels with the vessel. The Examiner characterizes Pickering as teaching that periodic, simulated blood pressure levels exist in the cuff. The Applicant respectfully disagrees. The Applicant submits that Pickering does not teach of any periodic pressure levels existing in the cuff, but rather teaches that the cuff is inflated as any conventional blood pressure measuring device using a cuff which is by a squeeze bulb or electrically operated pump (column 3, lines 28-32). Also in column 3, lines 53-55 Pickering states that the sphygmomanometer according to the invention may thus be operated in a manner which is virtually identical to that of conventional mechanical devices known in the art. Conventional squeeze bulbs for blood pressure cuff inflation have a dual check valve system (typically, one at the inlet of the bulb and one near the outlet) whereby the squeeze bulb acts as a one-way air pump to cause the cuff to inflate and to keep increasing the pressure inside the cuff as the bulb is manually compressed and released repeatedly. It is well known that the pressure inside of conventional blood pressure cuffs is not periodic but rather a monotonic function either increasing in pressure with time during inflation, or decreasing in time during deflation regardless if inflated by a squeeze bulb or an electric pump. The squeeze bulb or electric pump does not cause periodic pressure fluctuations inside the cuff that simulate human blood pressure fluctuations. For example, as a health care provider takes a patient's blood pressure using a blood pressure cuff, the pressure reading on the manometer or pressure gauge connected to the cuff does not fluctuate between the systolic and diastolic blood pressure levels of the patient, but rather makes a smooth increase in pressure value during the inflation of the cuff and a smooth increase during the deflation of the cuff. Further, the Applicant points to element 16 in Figure 1 of Pickering which is clearly labeled as a deflation knob further teaching his inflation bulb is of the conventional variety. In column 4 lines 20-26, Pickering teaches of an electronic control system that can automatically deflate the cuff at 2-3 mm of Hg per second, which is clearly a monotonic function and not a periodic function. Therefore, the Applicant submits that Pickering clearly teaches away from the Applicant's Claim 1 which, in part, is to provide in a pressure vessel cyclic pressure swings between simulated human diastolic and systolic pressures. Also it is noted that element 18 in Figure 1 is a systolic/diastolic switch to electronically record when the operator detects the systolic and diastolic blood pressure levels during deflation of the cuff (See columns 3 lines 45-50). The Applicant has amended Claim 1 to include the frequency of the periodic pressure amplitudes is the cardiac pulse rate of a human subject. The Applicant further submits that the apparatus of Pickering could not possibly be operated in this manner since it would be physically impossible to pump up a conventional blood pressure cuff to an accurate systolic pressure with the manual inflation bulb, manually open the bleed valve to bleed off air pressure in cuff to an accurate, prescribed diastolic pressure, manually close the bleed valve, and return the cuff to an accurate prescribed systolic pressure by manually pumping the inflation bulb (to complete one period) all on the order of less than one second which corresponds to a normal human cardiac pulse rate. For example, a normal human pulse rate of approximately 72 beats per minute corresponds to a period of 0.833 seconds. Some human pulse rates are as high as 96 beats per minute or more which would further shorten the period. It is well known that conventional sphygmomanometers take several seconds just to manually or electronically inflate the cuff from a human diastolic pressure level to a human systolic pressure, and this action only comprising approximately one-third of a complete simulated blood pressure cycle. The other two-thirds of the simulated cycle would be bleeding air from the cuff to an accurate diastolic pressure and then re-inflating the cuff to an accurate systolic pressure. Since Pickering clearly does not teach of the existence of periodic blood pressure levels between diastolic and systolic pressures being maintained inside a pressure vessel whereby a human can sense, through touch, pressure amplitudes within the pressure vessel (and, in fact, teaches away from this practice), and since the apparatus of Pickering or other conventional manual sphygmomanometers could not possibly be operated to perform the function or be of equivalent structure recited in Applicant's amended Claim 1 without very significant structural modifications, Pickering does not feature every element of amended Claim 1. Therefore the rejection under 102(b) is improper. The Applicant respectfully requests that the rejection be withdrawn and amended Claim 1 allowed.

Since Claim 13 has all of the limitations of the independent Claim 1 which has been amended, the Applicant submits that Claim 13 is now in condition for allowance for at least this reason.

Claims Rejections under 35USC §103(a):

Claims 1-4, 6, 10, 14, 15, 18-21, 23, 26, 28-31, 35-42, 44, 46, 48, 50-54, 56 & 57 are rejected by the Examiner under 35USC §103(a) as being unpatentable over Futcher et al (US 5,772,413) hereafter known as Futcher. The Applicant has amended the independent Claims 1, 19, 29, 36, 39, 42, and 57 to read over Futcher. The Applicant submits that Futcher limits his teaching to a device which must be squeezed by the user to increase the pressure in the deformable bulb 3 in Figure 1. That is, the pressure level in the bulb of Futcher is dependent upon if the user is compressing or releasing the bulb and how fast the user is periodically squeezing the bulb (column 6, lines 5-7), thus Futcher also teaches away from simulating simultaneously both accurate pulse rates and blood pressure levels. Futcher clearly teaches that the pressurized fluid within the bulb 3 is generated by manually compression of the same bulb. The Applicant has amended the rejected independent claims 1, 19, 29, 36, 39, and 57 to include the pressurized fluid in the Applicant's invention is generated external to the pressure vessel and the fluid pressure is conveyed inside the pressure vessel which the user handles to feel the periodic pressure level within the vessel. The Applicant further submits that the original specification of the application fully supports this amendment, for example see Figure 1. The Applicant submits that Claims 1, 19, 29, 39, and 57 as amended read over Futcher and respectfully requests that the rejections be withdrawn and the claims allowed.

Claim 42 recites the use of two elastomeric bulbs pneumatically connected whereby manual compression of one bulb controls the pressure in the second bulb. Since Futcher does not teach the use of more than one bulb and since he clearly teaches that the bulb which is compressed is also the bulb providing the tactile feedback to the user which is different than Claim 42, the Applicant respectfully submits that the 103(a) rejection is improper and should be withdrawn. Not every element of Claim 42 is taught by Futcher as a single reference to support the rejection. .

The remaining rejected Claims 2-4, 10,14, 15, 18, 20-21, 23, 28, 30-31, 35, 37-41, 44, 48, 50-54, & 56 are dependent claims depending on independent claims which have been traversed above. Claims 18 and 48 have been canceled. Since each of the above active dependent claims contains the limitation of their respective independent claims, it is requested for at least this reason that the rejections under 103(a) be withdrawn and the claims allowed.

The Examiner rejected Claims 7-9, 17, 22, 25, 27, 32-34, & 42 under 35 U.S.C. 103(a) as being unpatentable over Futcher (US 5,772,413), in view of claims 1, 19, & 29 and further in view of Pickering (US 6,168,567). Claim 42 is the only independent Claim in this group. The Examiner admits that Futcher fails to teach of a second hollow bulb or arm cuff connected to the first bulb such that the pressure in the second bulb is controlled by the amount of manual compression of the first bulb. The Examiner then goes on to state that Pickering teaches a sphygmomanometer using a conventional squeeze bulb to inflate an air bladder. As the Applicant has previously stated in this Amendment E, the sphygmomanometer system taught by Pickering uses a conventional squeeze bulb and cuff system whereby the air flow through the squeeze bulb is unidirectional to be able to inflate the cuff. Therefore, periodic compression and release of the squeeze bulb will only increase the pressure in the cuff and not decrease it. The Applicant has amended Claim 42 to include a bi-directional flow connection (element 230, connecting tubing which inherently provides bi-directional flow between bulbs 200 and 220). Further, the Applicant submits that combining the teachings of Futcher with Pickering would render the apparatus of Pickering non-functional for its purpose of measuring blood pressure since the cuff of Pickering could not be inflated properly. Finally, the Applicant submits there are no explicit or implicit motivations to combine the references of Pickering and Futcher and further, these references come from very different fields of use. The Applicant therefore submits that the teaching of Futcher in view of Pickering does not render amended Claim 42 obvious. The Applicant submits that the amended Claim 42 clearly defines over Futcher in view of Pickering. For the above reasons, the Applicant requests that the rejection for Claim 42 be withdrawn and the claim allowed. The Applicant also requests that the rejections for dependent claims 7-9, 22, 25, 27, & 32-34 be withdrawn since these claims include all the limitations of their respective independent claims which have been traversed elsewhere in this Amendment. Claim 17 has been canceled.

The Examiner rejected Claims 16, 45, 47, & 49 under 35 U.S.C. 103(a) as being unpatentable over Futcher (US 5,772,413), in view of claims 1, 19, & 29 and of Pickering (US 6,168,567) in view of claims 15, 44, 46, & 48 and in further view of Baldwin (US 4,773, 865), hereafter known as Baldwin. All of the claims in this rejection are dependent claims having the limitations of the independent claims or other dependent claims on which they depend. Claims

48 and 49 have been canceled since amended Claim 39 incorporates the elements of previously presented Claims 48 and 49. Since the independent claim rejections in this application have all been traversed, the Applicant submits that all active dependent claims are in condition for allowance. Further, as has been shown above by the Applicant, the combination of the teachings of Futcher and Pickering in an attempt to construct elements of the Applicant's invention would render Pickering's invention non-functional for its purpose. Baldwin does not teach that a simulated human diastolic or human systolic blood pressure level is produced in the apparatus or that such levels could even be discerned through touching of an artificial blood vessel. In order to combine references under 35USC 103(a) there must be some motivation in the prior art to combine the referenced cited to reject the cited claims. The references must be considered as a whole and must suggest the desirability and obviousness of making the combination. The Applicant submits that none of Futcher, Pickering, or Baldwin includes any motivation that they should be combined in a way that would arrive at the Applicant's Claims 16, 45, & 47. Nor has the Examiner provided a reason why there would be a motivation to combine the references and still maintain functionality of each individual reference. For the reasons listed above, the Applicant respectfully submits that the rejections of Claims 16, 45, & 47 are improper and requests that the rejections be withdrawn and the claims be allowed.

The Examiner rejected Claims 11, 43, & 55 under 35 U.S.C. 103(a) as being unpatentable over Futcher (US 5,772,413); in view of claims 1, 19, & 29 and of Pickering (US 6,168,567) in view of claims 10, 23, & 42 and in further view of Frazier (US 6,669,624), hereafter known as Frazier. All of the claims in this rejection are dependent claims having the limitations of the independent claims on which they depend. Since the independent claim rejections in this application have all been traversed, the Applicant submits that all dependent claims are in condition for allowance. Further, as has been shown above by the Applicant, the combination of the teachings of Futcher and Pickering in an attempt to construct elements of the Applicant's invention would render Pickering's invention non-functional for its purpose. The Applicant further submits that all of the claims on which Claims 11, 43, & 55 directly depend (Claims 10, 42, and 23, respectively) have as one limitation that a human hand must squeeze or grip the elastomeric bulb element of the Applicant's invention. This is very much different than the teaching of Frazier where he teaches that a catheter balloon is inflated inside a blood vessel of a human, not a bulb held by a human hand. The Applicant submits that the combination of Futcher and Frazier would render Frazier's invention non-functional since the catheter balloon of Frazier would not be able to inflate properly if Futcher's inflation system was used with Frazier's balloon catheter system. In order to combine references under 35USC 103(a) there must be some motivation in the prior art to combine the referenced cited to reject the cited claims. The references must be considered as a whole and must suggest the desirability and obviousness of making the combination. The Applicant submits that none of Futcher, Pickering, or Frazier includes any motivation that they should be combined in a way that would arrive at the Applicant's Claims 11, 43, & 55. Nor has the Examiner provided a reason why there would be a motivation to combine the references and still maintain functionality of each individual reference. Frazier is non-analagous art to the Applicant's invention since it unrelated to blood pressure demonstration or educational devices. For the reasons listed above, the Applicant respectfully submits that the rejections of Claims 11, 43, & 55 are improper and requests that the rejections be withdrawn and the claims be allowed.

The Applicant has traversed all of the independent claims active in the application and believes they are now in condition for allowance. Allowance is hereby requested. Further, the Applicant believes all dependent Claims are in condition for allowance for at least the reason that they contain all limitations of their respective independent claims. Allowance is hereby requested.

Summary

The Applicant has addressed each of the Examiner's rejections of the claims based on either by canceling claims, amending claims, or by traversing the rejections. The Applicant maintains that the Specification and knowledge of one having ordinary skill in the art fully enables the electronic control element and interface, but has amended related claims in order to advance the prosecution of this particular application in view of the Examiner's repeated rejections.

Pickering was shown as not teaching that periodic, simulated blood pressure levels exist in the cuff but rather he teaches use of a conventional cuff inflation system which inherently has unidirectional flow to the cuff, and in fact, teaches away from the existence of periodic pressures between simulated diastolic and systolic pressures in the cuff. Futcher was shown to teach that the same bulb that generates pressurized fluid is also used for a tactile interface. The Applicant amended claims to clearly define that the pressure generating element is external to the vessel providing the tactile interface and/or that the frequency of the periodic pressure excursions was that of a cardiac pulse of a human subject and/or the pneumatic flow between bulbs was bi-directional. It was shown that combining the teachings of Pickering and Futcher would render Pickering non-functional and that the combination of Futcher and Frazier would render Frazier non-functional.

The Applicant believes that all of the independent claims are now in condition for allowance and respectfully requests that the rejections be withdrawn and the claims allowed.

Also, since the dependent claims have included in them all limitations of the respective independent claims on which they depend, the Applicant respectfully submits that all of the active dependent claims are in condition for allowance and requests that the rejection for these claims be withdrawn.

If the Examiner believes that a telephone conversation would be useful to advance the prosecution of this application, the Applicant may be reached at (304)290-9942 at any time.

Respectfully Submitted,

Gary J. Morris, Ph.D.
Reg. No. 56,689
2026 Glenmark Avenue
Morgantown, WV 26505
(304)290-9942